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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,476	02/14/2002	David E. Chen	47777/GTL/B437	7531

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EXAMINER

HALE, GLORIA M

ART UNIT PAPER NUMBER

3765

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/075,476

Applicant(s)
Chen

Examiner
Gloria Hale

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 1,2,5,7-9 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Deal et al (6,231,423).

In regard to claims 1 and 20, Deal et al discloses a breast form (38,40) and the method of forming the breast form comprising a flexible chamber formed from a thermoplastic film (43,44) with a volume of silicone gel (42) sealably disposed within the flexible chamber (43,44) and fabric material (20,22) disposed over and permanently joined to the thermoplastic film material (43,44) at lip (46). (See Deal et al., col. 3, lines 40-67 and figures 2,4 and 6).

In regard to claims 2 and 9, the thermoplastic film layers of Deal et al., are sealed together as claimed. (See Deal et al., col. 3, lines 53-58).

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In regard to claims 5 and 8, Deal et al. discloses the breast form structure as claimed and as discussed above in regard to claim 1 (See Deal et al., col. 3, lines 40-60) and also discloses the fabric layer and thermoplastic film layer as being laminated. (See Deal et al., col. 3, lines 60-67 and figures 2,4 and 6). In regard to claim 7, Deal et al., discloses the film (43,44) as being of polyurethane (col. 4, line 10).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3,6,14,15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deal et al in view of Ishikawa et al (6,042,608).

In regard to claims 3,6,14 and 18, Deal et al discloses the invention substantially as claimed.

However, Deal et al does not specifically disclose the fabric material as being a 4-way stretch material. Ishikawa et al discloses a gel bra pad with a polyurethane layer covered by a raschel knit (a 4 way stretchable material) which is commonly used in undergarment manufacturing for comfort and aesthetics. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pad of Deal et al to use a fabric layer of a 4-way stretch as disclosed in Ishikawa for comfort and aesthetics which would allow for the

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movement of the gel within. In regard to claim 15, Deal et al discloses the polyurethane film as claimed.

5. Claims 16, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deal et al in view of Ishikawa et al as applied to claims 14, 15 and 18 above, and further in view of Naestoft (5,071,433).

In regard to claims 16, 17 and 19, Deal et al and Ishikawa et al disclose the fabric and polyurethane film covered gel pad. However, Deal et al does not disclose the pad without the bra cup construction wherein the pad is attached to the wearer's skin. Naestoft et al discloses attaching a breast gel pad directly to a wearer with the use of well known polymer adhesives such as CURAGUARD to adhere the prosthetic to the exact and best position on a wearer. The material would inherently adhere to the material layer on the prosthesis with a greater cohesion force than to the wearer's skin in that the inherent moisture on the wearer's skin (sweat) would wear down the adhesive and the adhesive would remain on the fabric layer longer than on the wearer and the adhesive force to the skin of the wearer is less than on the fabric. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pad of Deal et al to use it directly onto a wearer instead of in a bra construction with the use of adhesive as disclosed by Naestoft et al in order to better place the pad on the wearer and so that the pad does not move from the wearer as it would when in a bra structure. (See Naestoft et al., col. 3, line 35 - col. 4, line 2 and col. 1, lines 28-37)

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9. Claims 12 and 13 are rejected under 35 U.S.C. 103 9a) as being unpatentable over Deal et al in view of Naestoft et al (5,701,433).

In regard to claims 12 and 13, Deal et al discloses the fabric and polyurethane film covered gel pad. However, Deal et al does not disclose the pad without the bra cup construction wherein the pad is attached to the wearer's skin. Naestoft et al discloses attaching a breast gel pad directly to a wearer with the use of well known polymer adhesives such as CURAGUARD to adhere the prosthetic to the exact and best position on a wearer. The material would inherently adhere to the material layer on the prosthesis with a greater cohesion force than to the wearer's skin in that the inherent moisture on the wearer's skin (sweat) would wear down the adhesive and the adhesive would remain on the fabric layer longer than on the wearer and the adhesive force to the skin of the wearer is less than on the fabric. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pad of Deal et al to use it directly onto a wearer instead of in a bra construction with the use of adhesive as disclosed by Naestoft et al in order to better place the pad on the wearer and so that the pad does not move from the wearer as it would when in a bra structure. See Naestoft et al., col. 3, line 35 - col. 4, line 2 and col. 1, lines 28-37).

6. Claims 4, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deal et al.

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In regard to claims 4, 10 and 11, Deal et al discloses the invention substantially as claimed and as discussed above. However, Deal et al does not specifically disclose the use of a gel with a low density filler greater than 40 percent or less than 60 percent organo-polysiloxane.

Deal et al discloses the use of 40 percent low density filler. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a silicone gel pad with greater than 40 percent low density filler and less than 60 percent organo-polysiloxane to achieve the desired aesthetic effect and to find the appropriate consistency mixture through routine experimentation in order to best simulate a breast. (See Deal et al., cols. 4-5).

Response to Arguments

7. Applicant's arguments filed 8-20-03 have been fully considered but they are not persuasive.

Applicant's remarks of page 9, lines 5-7 state that the structure is a breast form as broadly claimed including a flexible chamber formed from a thermoplastic film material and a fabric material which forms the breast form in that it is the part which forms the breast form simulated shape. Applicant is arguing more than what is claimed. The claim does not state that the fabric material is disposed over and permanently joined over the entire surface or that the laminated layers are over the entire surface. It is only permanently joined as claimed by the anchoring as disclosed by Deal et al and as claimed in claims 1, 5, 18 and 20. The present claim 1 is extremely broad and does not recite over the present prior art in the rejections.

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8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gloria Hale whose telephone number is (703) 308-1282.


Gloria Hale

Primary Patent Examiner- AU 3765

October 31, 2003